SUPPLEMENTAL DECLARATION OF
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I was provided with documents for comment that were filed in court by the State of Missouri. The documents are a statement indicating that an unknown laboratory is accredited by The American Association for Laboratory Accreditation; Scope of Accreditation To ISO/IEC 17025:2005; and a Certificate Of Analysis for pentobarbital sodium 50 mg/ml solution.

Specific Comments

1. The American Association for Laboratory Accreditation states on its Web site that it "is a nonprofit, non-governmental, public service, membership society. A2LA also offers programs for the accreditation of testing laboratories, calibration laboratories, inspection bodies, proficiency testing providers, medical testing laboratories, reference material producers and product certification bodies."

   This organization appears to be in the business of providing programs for commercial analytical laboratories to become accredited by The American Association for Laboratory Accreditation. Their qualifications for conducting analytical testing of pharmacy-compounded drugs are unknown.

   To the best of my knowledge I am not aware of any drug regulatory authority (either the Food and Drug Administration or State Boards of Pharmacy) that recognize accreditation by The American Association for Laboratory Accreditation.

2. The second document titled Scope Of Accreditation lists the tests that a commercial analytical laboratory would be qualified to perform when accredited by The American Association for Laboratory Accreditation.

3. The Certificate Of Analysis for pentobarbital sodium appears to come from an unknown commercial analytical laboratory and indicates a concentration of 50.490 mg/ml. A statement appears on this document that the method used in this determination was not validated. This is concerning because it erodes confidence in the reported concentration.

   The documents provided by the Missouri Department of Corrections leave a number of critical questions concerning the quality of this pharmacy compounded pentobarbital sodium unanswered.

A. What is the source of the pentobarbital sodium active pharmaceutical ingredient (API)?

B. Does this pentobarbital sodium API meet USP standards?

C. Was this pentobarbital sodium produced in a Food and Drug Administration facility meeting Good Manufacturing Practice Guidelines?

D. Was the compounded pentobarbital sodium produced in a facility that would assure that cross-contamination would not occur with drugs that could cause potentially serious allergic reactions?

E. Why was this pentobarbital sodium not tested for adulterants, endotoxins, and sterility?

CONCULSION

Recent events have place the quality of analyses performed by commercial analytical laboratories in question. The Washington Post on October 5, 2013 reported the FDA cited five commercial analytical laboratories for more than 70 safety problems. These five laboratories conduct testing for about 90 percent of the large compounding pharmacies in the US. Dozens of types of drugs, packaged in thousands of IV bags, syringes and vials, have been recalled as a result of FDA inspections at the compounding pharmacies and the laboratories they use.

The documents provided by the Missouri Department of Corrections only indicate that the product that was tested may contain pentobarbital sodium. There is no indication that this product was sterile, free from cross-contamination or other adulterants that could pose a serious risk to the prisoner receiving an injection of this product.

I certify that the statements made above are accurate and true under penalty of perjury.

/s/ Larry D. Sasich

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